



DuPont Agriculture & Nutrition
Pioneer Emerson Building
7250 N.W. 62nd Ave.
P.O. Box 552
Johnston, IA 50131-0552
(515) 270 3202 Tel

October 17, 2002

Mr. Phil Hutton
U.S. Environmental Protection Agency
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
Document Processing Desk (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: *BACILLUS THURINGIENSIS* Cry34/35Ab1 INSECTICIDAL CRYSTAL PROTEINS AS
EXPRESSED IN MAIZE (Construct PHP17658)
REQUEST FOR NEW EXPERIMENTAL USE PERMIT (029964-EUP-U)

Dear Mr. Hutton:

Pioneer Hi-Bred International, Inc. is hereby submitting a new application for an Experimental Use Permit to field test the plant-pesticide *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 insecticidal crystal protein (*B.t.* Cry34/35Ab1) as expressed in maize. Maize plants expressing the plant-pesticide were developed by Pioneer and Mycogen Seeds c/o Dow AgroSciences LLC (Mycogen). We are requesting this EUP with authorization to cite data submitted by Mycogen for a corresponding EUP. Study reports in support of this EUP application are being submitted with Mycogen's EUP (68467-EUP-T).

The "active ingredient" in the plant-pesticide that is the subject of this EUP request is *B. t.* Cry34/35Ab1 insecticidal crystal protein and the genetic material necessary for their production in maize (PHP17658). Small-scale field tests have shown that Cry34/35Ab1 expressed in maize is very effective in controlling Western corn rootworm and Northern corn rootworm.

This proposed EUP program will cover plantings of maize derived from transformation events using plasmid construct PHP17658 across 19 states from March 2003 to March 2004, for a total of 622,427 acres. The breakdown of acreage in each state and the number of locations in each state is provided in Proposed Experimental Program, Section G of this submission.

A temporary tolerance petition was previously submitted (March 2001) and is currently under review at EPA. All activities for this EUP will be conducted on a 'non-crop destruct' basis for food and feed use, but will maintain 'crop-destruct' for environmental containment.

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Please note that the expression values listed on the Confidential Statement of Formula are research values from research studies conducted either in the field or greenhouse. The purpose of the EUP is to allow more research studies to be conducted to generate the necessary information and data to submit a registration package. Results from GLP-conducted field expression studies will be provided with the full registration package.

We are identifying the confidentiality classification for the studies we are submitting today as 'B'. Additionally, we are identifying the confidentiality classification of the Confidential Statement of Formula, data matrix and proposed labeling as 'C'. The Proposed Experimental Program document has the confidentiality classification of 'A', except for the confidential appendix, which is classified as 'C'.

Contents of Submission

Volume Number	Contents
Volume 1 (Administrative)	Transmittal document (this letter) Application for Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only, EPA Form 8570-17 (OPP No. 202684) Substantiation for claim of confidentiality dated October 17, 2002 Certification with Respect to Citation of Data (EPA Form 8570-34) dated October 17, 2002 Basic Confidential Statement of Formula (EPA Form 8570-4) dated October 17, 2002 Data Matrix for Pioneer Brand <i>B.t.</i> Cry34/35Ab1 Corn (Construct PHP 17658) (EPA Form 8570-35) dated October 17, 2002 (CBI and CBI deleted copies) Section A (Product Characterization) Data in support of this section is contained in the bridging documents entitled "Section A: Product Characterization" and Volume(s) 3-5 of Mycogen's EUP 68467-EUP-T Section B (Proposed Labeling) See enclosed proposed labeling for Pioneer Brand <i>B.t.</i> Cry34/35Ab1 Corn (Construct PHP17658) (1 copy) Section C (Toxicology Data) Data in support of this section is contained in bridging documents entitled "Section C: Toxicology Data"

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Volume Number Contents

Volume 1
(continued)

Section D (Residue and Environmental Data)
See Volume 11 of Mycogen's EUP 68467-EUP-T

Section E (Product Performance Data and Product Durability Plan)
Data in support of this section is contained in bridging document
entitled "Section E: Product Performance and Product Durability
Plan" and Volume(s) 12-14 of Mycogen's EUP 68467-EUP-T

Section F (Tolerance Proposal)
See statement under Section F

Section G (Proposed Experimental Program)
See Volume 2 of this application

Volume 2 Proposed Experimental Program
 Pages: 1-30 (3 copies)

Below is a list of studies, which are being cited for this submission. Some of these studies were submitted today with the request for a new experimental use permit for *B.t.* Cry34/35Ab1 insecticidal crystal protein as expressed in maize (Construct PHP17658) (Mycogen's EUP 68467-EUP-T) and are classified as confidentiality classification 'B'.

MRID No.	Contents
Submitted 10/17/02	Product Characterization Data for <i>Bacillus thuringiensis</i> Cry34Ab1 and Cry35Ab1 Proteins Expressed in Transgenic Maize Plants (PHP17658) Coats, I. and Herman, R.A. October 15, 2002 Study ID: PHI-2002-047 Pages: 1-283 (3 copies)
Submitted 10/17/02	Characterization of Cry34Ab1 and Cry35Ab1 from Recombinant <i>Pseudomonas fluorescens</i> and Transgenic Maize Schafer, B.W. October 3, 2002 Study ID: GH-C 5545 Pages: 1-17 (3 copies)

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Submitted 10/17/02	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms Higgins, L. October 11, 2002 Study ID: PHI-2002-056 Pages: 1-13 (3copies)
Submitted 10/17/02	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Ab1 Proteins Expressed in Maize Plants Transformed with the Vector PHP17658 Essner, R. October 14, 2002 Study ID: PHI-2002-048 Pages: 1-110 (3 copies)
Submitted 10/17/02	Characterization of DNA Inserted into Transgenic Corn Events E4497.42.1.34, E4497.45.2.16, E4497.59.1.10, E4497.66.1.27, E4497.71.1.29, and E4497.71.1.33 Locke, M.E. and Nirunsuksiri, W. October 10, 2002 Study ID: GH-C 5550 Pages: 1-26 (3 copies)
Submitted 10/17/02	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (<i>Nasonia vitripennis</i>) Porch, J.R., et al September 28, 2001 Study ID: 011105 (379-115) Pages: 1-27 (3 copies)
Submitted 10/17/02	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Walbaum Marino, T.A. April 3, 2002 Study ID: 011193 Pages: 1-31 (3 copies)
Submitted 10/17/02	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i> Straus Marino, T.A. September 5, 2001 Study ID: 011137 Pages: 1-28 (3 copies)
Submitted 10/17/02	Assessment of Chronic Toxicity of Diet Containing <i>Bacillus thuringiensis</i> PS149B1 Insecticidal Crystal Protein to Collembola (<i>Folsomia candida</i>) Teixeira, D October 9, 2001 Study ID: 011106 Pages: 1-35 (3 copies)
Submitted 10/17/02	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae (<i>Chrysoperla carnea</i>) Sindermann, A.B., et al November 9, 2001 Study ID: 379-116A Pages: 1-30 (3 copies)

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MRID No.	Contents
Submitted 10/17/02	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212 Herman, R.A., <i>et al.</i> September 9, 2002 Study ID: GH-C 5513 Pages: 1-11 (3 copies)
Submitted 10/17/02	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Ab1 and Cry35Ab1 Storer, N.P. September 26, 2002 Study ID: GH-C 5506 Pages: 1-14 (3 copies)
45242207	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice Brooks, K.J. and DeWildt, P.M. October 10, 2000 Study ID: 001130
45242204	Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study Herman, R.A. September 26, 2000 Study ID: 000366 (GH-C 5114)
45242208	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice Brooks, K.J. and DeWildt, P.M. October 10, 2000 Study ID: 001129
45242209	PS149B1 14 KDA and 44 KDA Proteins: Acute Oral Toxicity Study in CD-1 Mice Brooks, K.J. and DeWildt, P.M. October 10, 2000 Study ID: 001128
45242212	<i>In Vitro</i> Digestibility of PS149B1 Proteins Korjagin, V.A. and Ernest, A.D. October 6, 2000 Study ID: 000302 (GH-C 5132)
45584502	<i>In Vitro</i> Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein Korjagin, V.A. <i>et al.</i> January 8, 2002 Study ID: 010111 (GH-C 5361)
45242205	Comparison of the Amino Acid Sequence of the Bacillus thuringiensis Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens Stelman, S.J. October 13, 2000 Study ID: GH-C 5140

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45358401	Thermolability of PS149B1 Binary Delta-Endotoxin Herman, R. March 19, 2001 Study ID: 001041
45584501	Heat Lability of Individual Proteins of the PS149B1 Binary ICP Herman, R. January 7, 2002 Study ID: 010144 (GH-C 5360)
45340701	Microbial PS149B1 Binary Insecticidal Crystal Protein, Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 14kDa and 44kDa Insecticidal Crystal Proteins: Evaluation of Dietary Exposure on Honeybee Development Maggie, V. January 28, 2001 Study ID: CAR 149-00
45242210	PS149B1 Binary Insecticidal Crystal Protein: A Dietary Toxicity Study with the Ladybird Beetle Bryan, R.L., <i>et al</i> September 3, 2000 Study ID: 379-103 (000155)
45242211	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, Corn Leaf Aphid and Ladybird Beetle Higgins, L. October 6, 2000 Study ID: PHI-2000-022
45360201	PS149B1 Binary Insecticidal Crystal Protein: Acute Toxicity to the Earthworm in an Artificial Substrate Bryan, R., <i>et al</i> March 19, 2001 Study ID: 379-104
45242214	Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region Herman, R.A., <i>et al</i> October 15, 2000 Study ID: 000365 (GH-C 5113)

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Claims of confidentiality as listed in Section 2.204(e)(4) of 40 CFR, part 174, subpart A

1) The portions of the information which are alleged to be entitled to confidential treatment

Pioneer Hi-Bred International, Inc. (Pioneer) requests confidentiality of the names, locations and addresses of field trials and cooperators contained in the Confidential Appendix attached to the Section G of the EUP submission.

2) The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event, or permanently)

Pioneer requests that the information referenced in 1) be kept confidential permanently due to the following:

Pioneer uses the same field/farm sites for many of the products in its development pipeline. Disclosure of the location and characteristics of the field, and the experiments conducted thereon, would provide competitors with invaluable information about our product development marketing strategy and could cause severe harm to Pioneer's competitive standing in the industry for all products currently in the development pipeline.

Moreover, security has been a serious issue in many locations where biotechnology products are developed and tested. As the Agency is aware, many field test plots have been destroyed by those generally opposed to research on, and marketing of, products of biotechnology. Accordingly, for security reasons, Pioneer also requests that the requested information be kept confidential indefinitely.

3) The purpose for which the information was furnished to EPA and the approximate date of submission, if known.

The cooperators' names, field trial locations and nature of field trials are being disclosed to EPA as a requirement of the Experimental Use Permit (EUP) application process. The information is being furnished to EPA as part of our application for Experimental Use Permit 29964-EUP-U (dated October 17, 2002).

4) Whether a business confidentiality claim accompanied the information when it was received by EPA.

The cover letter that accompanies this application for Experimental Use Permit 29964-EUP-U, and all subsequent cover letters for requesting amendment of this Experimental Use Permit, has claimed the items referenced in the Confidential Appendix attachment to the Section G as Confidential Business Information.

5) Measures taken by the business to guard against undesired disclosure of the information to others.

Except for the necessary disclosure to cooperators and collaborators under confidentiality agreements with Pioneer, no disclosure of the confidential information has been knowingly made by Pioneer to anyone other than EPA and USDA-APHIS.

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6) The extent to which the information has been disclosed to others, and the precautions taken in connection therewith.

Except for the necessary disclosure to cooperators and collaborators under confidentiality agreements with Pioneer, no disclosure of the confidential information has been knowingly made by Pioneer to anyone other than EPA and USDA-APHIS.

7) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies, and a copy of any such determination, or reference to it, if available.

No pertinent confidentiality determinations have been made.

8) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business' competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects.

Disclosure of the location, characteristics and time of the field experiments would provide competitors with invaluable information about Pioneer's marketing strategy and could cause severe harm to Pioneer's competitive standing in the industry. This information provides a competitor with access to our trials and information on the size and maturity of our program and information that could be utilized to determine when our product would enter the marketplace. Information on the location of the field experiments will directly, with little or no effort, provide the identity of cooperators and collaborators. Release of the cooperator and collaborator identities provides the competition with knowledge about individuals and organizations that Pioneer has found to be expert in the area of biotechnology. There is no doubt that competitors would seek to utilize the services of the entities found to be the most expertly qualified by Pioneer and limit or block Pioneer's access to these sources. Also, maintaining the safety and good will of the cooperators and collaborators is an important consideration for our business success. The release of information that would directly or indirectly identify the cooperators and collaborators could cost Pioneer considerable good will and the breach of any agreement with the cooperators and collaborators. This could lead to the loss of an entity as an expert source, thereby forcing Pioneer to use alternative cooperators and collaborators. It would take time to identify high technical performance, and it would represent a loss of the valuable expertise and understanding built up with former cooperators and collaborators. Consequently, this could result in a delay in bringing products to market, which would cost Pioneer sums in the millions of dollars.

9) Whether the business asserts that the information is voluntarily submitted information as defined in Sec. 2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

According to 40 CFR § 2.201(i) "voluntarily submitted" information means business information in the EPA's possession:

1. The submission of which EPA had no statutory or contractual authority to require; and
2. The submission of which was not prescribed by statute or regulation as a condition of obtaining some benefit (or avoiding some disadvantage) under a regulatory program of general applicability, including such regulatory programs as permit, licensing, registration, or certification programs, but excluding programs concerned solely with the award or administration by EPA of contracts or grants.

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After reviewing 40 CFR § 2.201(i), Pioneer states that the information identifying the location of the fields and farms in EUP 68467-EUP-2 was not voluntarily submitted to the EPA. Regulatory requirements set forth in 40 CFR § 180.1001 require that such information be provided to the EPA in order to obtain an EUP and registration for the product.

The claims of confidentiality submitted in this letter are presented in good faith and are believed to be accurate. We believe that any justification requirements have been fully met, that disclosure of Pioneer-designated **Confidential Business Information** by the EPA would be without legal authority and would result in immediate and irreparable substantial harm to Pioneer.

If the EPA determines that there are deficiencies in Pioneer's responses to EPA's questions concerning Pioneer's claims of confidentiality, we request that the EPA point out the alleged deficiencies in sufficient detail so as to be clearly understood, together with an explanation as to why the same are to be considered deficiencies. **We also request that Pioneer be provided a reasonable opportunity to respond to such deficiencies.**

If, upon consideration, the EPA eventually chooses not to honor Pioneer's claim of confidentiality, we request that the EPA document on the record all of its findings and conclusions and its reasons for reaching an adverse decision. Documentation of an adverse decision must be extensive enough that an appellate body could review the record and determine if there was substantial evidence in support of the EPA's position.

IN THE EVENT THE EPA CONTEMPLATES DISCLOSURE OF INFORMATION CONSIDERED BY PIONEER TO BE CONFIDENTIAL TO ANY PERSON OR ORGANIZATION, PUBLIC OR PRIVATE, WE REQUEST THAT NOTICE BE GIVEN TO PIONEER AT LEAST FIFTEEN (15) BUSINESS DAYS PRIOR TO SUCH DISCLOSURE BEING MADE.

We trust that Pioneer and Mycogen Seeds can work closely with the EPA so that both applications will be reviewed in sufficient time to grant approval by spring planting in 2003.

If you require further information, please contact me at 515-270-5983 or Larry Zeph, Registration Coordinator, at 515-253-5807.

Sincerely,


Isabelle S. Coats
Associate Registration Manager

Enclosures

Cc: Mike Mendelsohn, EPA

VOLUME 1

PHP17658



United States
ENVIRONMENTAL PROTECTION AGENCY
 Washington, DC 20460

OPP Identifier Number

Office of Pesticides Programs (7505C)
Application for Experimental Use Permit to Ship and
Use a Pesticide for Experimental Purposes Only

1. Type of Application



New



Amendment (See No. 2)



Extension (Give Permit Number below)

Permit Number

2. Briefly explain (Attach a separate sheet if necessary)

1. Request for new EUP for B.t. Cry34/35Ab1 construct PHP17658 insecticidal crystal protein derived from *Bacillus thuringiensis*.

2. Request for non-crop destruct status for food and feed use and crop destruct for environmental containment.

3. Name and Address of Firm/Person to Whom the Experimental Use Permit is to be Issued (Include Zip Code) (Type or Print)

Pioneer Hi-Bred International, Inc.
 c/o Isabelle S. Coats
 7250 NW 62nd Avenue
 Johnston, IA 50131

4. Name and Address of Shipper only if shipment is intended or if different from applicant's name and address (include Zip Code) (Type or Print)

EPA Company Number 29964

5. Name of Product

Pioneer Brand B.t. Cry34/35Ab1 Corn (Construct
 PHP17658)

6. Is Product Registered with EPA?



No



Yes (Give Registration Number or File Symbol below)

Registration Number

File Symbol

Total Quantity of Product Proposed for Shipment/Use
 Pounds of formulated product 10,375.858

Pounds of active ingredient 152.93g/Cry34Ab1; 7.952g Cry35Ab1

8. Acreage or Area to be Treated

622.427

9. Proposed Period of Shipment/Use

March 2003 - March 2004

10. Places from which Shipped

Any Pioneer Hi-Bred International, Inc. seed facility in
 the U.S.

11. Crop/Site to be Treated

Maize

12. Specify the name and number of the contact person most familiar with this application.

Isabelle S. Coats, 515-270-5983

13. Signature of Applicant or Authorized Firm Representative

14. Title

Associate Registration Manager

15. Date Signed

10-17-2002

Certification

This is to certify that food or feed derived from the experimental program will not be used or offered for consumption or sale for consumption, except by laboratory or experimental animals, if illegal residues are present in or on such food or feed.

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both, under applicable law

Below for EPA Use Only

In any correspondence on this application, refer to this number

Received by:
 EPA-OPP Registration Division,
 Washington, DC 20460

Normal review time indicates that processing of this application should be completed by (date)

Name of EPA Contact Person

Telephone Number



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Pioneer Hi-Bred International, Inc., 7250 NW 62nd Av, Johnston, IA 50131, 515-270-5983	EPA Registration Number/File Symbol 29964-EUP-U
Active Ingredient and/or representative test compound(s) B.t. Cry34/35Ab1 insecticidal crystal protein and the genetic material necessary for its production in maize (Construct PHP17658)	Date October 17, 2002
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name Pioneer Brand B.t. Cry34/35Ab1 Corn (Construct PHP17658)

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>J S Coats</i>	Date October 17, 2002	Typed or Printed Name and Title Isabelle S. Coats Associate Registration Manager
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401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date **October 18, 2002**

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Applicant's/Registrant's Name & Address Pioneer Hi-Bred International, Inc., 7250 NW 62nd Avenue, PO Box 552, Johnston, IA 50131; 515-270-5983

Pioneer® Brand B.t. Cry34/35Ab1 Corn (Construct PHP17658)

Ingredient *Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal protein and the genetic material necessary for its production in maize (PHP17658)

[illegible]

Signature

Name and Title

Name and Title
Isabelle S. Coats, Associate Registration Manager

Date _____

EPF Form 8570-36 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

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Date	October 18, 2002	EPA Reg No./File Symbol	029964-EUP-U	Page 2	of 5
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Pioneer Hi-Bred International, Inc., 7250 NW 62nd Avenue, PO Box 552, Johnston, IA 50131; 515-270-59833		Pioneer® Brand B.t. Cry34/35Ab1 Corn (Construct PHP17658)			
Ingredient <i>Bacillus thuringiensis</i> Cry34/Cry35Ab1 insecticidal crystal protein and the genetic material necessary for its production in maize(PHP17658)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature		Name and Title		Date	
		Isabelle S. Coats, Associate Registration Manager		10/18/02	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATA MATRIX

Date	October 18, 2002	EPA Reg No./File Symbol	029964-EUP-U	Page 3	of 5
Applicant's/Registrant's Name & Address	Pioneer Hi-Bred International, Inc., 7250 NW 62nd Avenue, PO Box 552, Johnston, IA 50131; 515-253-5807	Product	Pioneer® Brand B.t. Cry34/35Ab1 Corn (Construct PHP17658)		
Ingredient <i>Bacillus thuringiensis</i> Cry34/35Ab1 insecticidal crystal protein and the genetic material necessary for its production in maize(PHP17658)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature	Isabelle S. Coats, Associate Registration Manager			Date	
				10/18/02	



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DATA MATRIX

Date	October 18, 2002	EPA Reg No./File Symbol	029964-EUP-U	Page 4	of 5
Applicant's/Registrant's Name & Address		Product			
Pioneer Hi-Bred International, Inc., 7250 NW 62nd Avenue, PO Box 552, Johnston, IA 50131; 515-253-5807		Pioneer® Brand B.t. Cry34/35Ab1 Corn (Construct PHP17658)			
Ingredient <i>Bacillus thuringiensis</i> Cry34/35Ab1 insecticidal crystal protein and the genetic material necessary for its production in maize (PHP17658)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	
Signature <i>Isabelle S. Coats</i>		Name and Title		Date	
		Isabelle S. Coats, Associate Registration Manager		10/18/02	



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DATA MATRIX

Date	October 18, 2002	EPA Reg No./File Symbol	029964-EUP-U	Page 5	of 5
Applicant's/Registrant's Name & Address		Product			
Pioneer Hi-Bred International, Inc., 7250 NW 62nd Avenue, PO Box 552, Johnston, IA 50131; 515-253-5807		Pioneer® Brand B.t. Cry34/35Ab1 Corn (Construct PHP17658)			
Ingredient <i>Bacillus thuringiensis</i> Cry34/35Ab1 insecticidal crystal protein and the genetic material necessary for its production in maize (PHP17658)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
Signature <i>[Signature]</i>			Name and Title		Date
			Isabelle S. Coats, Associate Registration Manager		10/18/02

SECTION A. PRODUCT CHARACTERIZATION

Experimental Use Permit

***Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal proteins as expressed in maize**

See Volume(s) 3–5 of Mycogen's EUP 68467-EUP-T and MRID# 45242204

Section A: Product Characterization

Maize-Insect-Pest Susceptibility

Bridging of Insect-Pest-Spectrum Data

Data illustrating the insect-pest spectrum for the Cry34Ab1 and Cry35Ab1 proteins were reported under Laboratory study ID 000366 (MRID Number 45242204).

The *cry34Ab1* and *cry35Ab1* genes code for the same Cry34Ab1 and Cry35Ab1 proteins as those characterized in Narva *et al.*, 2000 (MRID Number 45242201). Codon changes were made to lessen the likelihood of open reading frames (ORFs) in the gene inserts; however, the protein sequence and activity of the insecticidal crystal protein were not altered.

Because the proteins share identical amino acid sequences, the insect-pest-spectrum data contained in MRID Number 45242204 support this new EUP application. These data illustrate the insect-pest-spectrum of Cry34Ab1 and Cry35Ab1 proteins.

Study Title	MRID Number
Microbial PS149B1 Binary Delta-Endotoxin: Maize-Insect-Pest Susceptibility Study	45242204

SECTION B. PROPOSED LABELING

Experimental Use Permit

***Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal proteins as expressed in maize**

Pioneer Brand *B.t.* Cry34/35Ab1
EPA Reg. No. 029964-EUP-____

Registration Notes:

Draft label for new EUP for *B.t.* Cry34/35Ab1 (March 2003 to March 2004)

THIS LABEL IS NOT FOR DISTRIBUTION

SECTION C. TOXICOLOGY DATA

Experimental Use Permit

***Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal proteins as expressed in maize**

See MRID# 45242207, 45242208, 45242209, 45242212, 45584502, 45242205, 45358401,
45584501, 45242210, 45242211, 45340701, and 45360201

Section C: Toxicology Data

Toxicity to Humans and Non-target Organisms

Bridging of Toxicity Data

The *cry34Ab1* and *cry35Ab1* genes code for the same Cry34Ab1 and Cry35Ab1 proteins as those characterized in Narva *et al.*, 2000 (MRID Number 45242201). Codon changes were made to lessen the likelihood of open reading frames (ORFs) in the gene inserts. The codon changes did not alter the structure or conformation of the proteins, as the protein sequence and activity of the insecticidal crystal protein were not altered.

Based on the above, the specificity (i.e., toxicity toward target pests) of the Cry34Ab1 and Cry35Ab1 proteins expressed in transgenic maize plants is expected to be similar.

Preliminary data indicate that the Cry34Ab1 protein is expressed in similar amounts in the tissues analyzed for transgenic events derived from construct PHP17658 as in events derived from PHP14352 (MRID Number 45242213). Events derived from construct PHP17658 are subject of this EUP application; see Essner, 2002 (PHI-2002-048).

Preliminary data indicate that the Cry35Ab1 protein is expressed in significantly reduced amounts in the tissues analyzed for transgenic events derived from construct PHP17658 compared to events derived from PHP14352 (MRID Number 45242213). PHP17658 is subject of this EUP application; see Essner, 2002 (PHI-2002-048). However, testing with bacterially prepared Cry34Ab1 and Cry35Ab1 proteins at levels greatly exceeding the expression of both proteins in transgenic maize plants resulted in no effect with several beneficial species. Therefore, the data below adequately address toxicity to humans and nontarget organisms to support this new EUP.

The table below lists study titles and MRID numbers for toxicity data generated for the Cry34Ab1 and Cry35Ab1 proteins and specific for transgenic maize plant tissues containing these proteins.

Toxicity Studies

Study ID	Study Title	MRID Number
001130	PS149B1 14 kDa Protein: Acute Oral Toxicity Study in CD-1 Mice	45242207
001129	PS149B1 44 kDa Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208
001128	PS149B1 14 kDa and 44 kDa Proteins: Acute Oral Toxicity Study in CD-1 Mice	45242209
000302 (GH-C-5132)	<i>In vitro</i> Digestibility of PS149B1 Proteins	45242212
010111	<i>In vitro</i> Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Ab1 Protein	45584502
GH-C- 5140	Comparison of the Amino Acid Sequence of the <i>Bacillus thuringiensis</i> Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Allergens	45242205
001041	Thermolability of PS149B1 Binary Delta-Endotoxin	45358401
010144	Heat Lability of Individual Proteins of the PS149B1 Binary ICP	45584501
379-103 (000155)	PS149B1 Binary Insecticidal Crystal Protein: A Dietary Toxicity Study with the Ladybird Beetle	45242210
PHI-2000-022	The Tri-Trophic Interaction Between PS149B1 Transformed Maize, CornLeaf Aphid and Ladybird Beetle	45242211
CAR 149-00	Microbial PS149B1 Binary Insecticidal Crystal Protein, Pollen Expressing PS149B1 Binary Insecticidal Crystal Protein, and Individual PS149B1 14 kDa and 44 kDa Insecticidal Crystal Proteins: Evaluation of Dietary Exposure on Honeybee Development	45340701
379-104	PS149B1 Binary Insecticidal Crystal Protein: Acute Toxicity to the Earthworm in an Artificial Substrate	45360201
GH-C 5513	SDS-PAGE Sensitivity Analysis for Cry35Ab1 in Support of Simulated Gastric Fluid Digestion Study; MRID#45242212	
011193	PS149B1 Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Walbaum	
011137	PS149B1 Binary Insecticidal Crystal Protein: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i> Straus	
379-115	PS149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (<i>Nasonia vitripennis</i>)	
011106	Assessment of Chronic Toxicity of Diet Containing <i>Bacillus thuringiensis</i> PS149B1 Insecticidal Crystal Protein to Collembola (<i>Folsomia candida</i>)	
379-116A	PS149B1 Insecticidal Crystal Protein: Dietary Toxicity to Green Lacewing Larvae (<i>Chrysoperla carnea</i>)	

SECTION D. RESIDUE AND ENVIRONMENTAL DATA

Experimental Use Permit

***Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal protein as expressed in maize**

See Volume 11 of Mycogen's EUP 68467-EUP-T

SECTION E. PRODUCT PERFORMANCE DATA AND PRODUCT DURABILITY PLAN

Experimental Use Permit

***Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal protein as expressed in maize**

See Volume(s) 12-14 of Mycogen's EUP 68467-EUP-T and MRID # 45242214

Section E: Product Performance and Product Durability Plan

Degradation in Soil

Bridging of Soil-Degradation Data

Data illustrating the degradation of the Cry34Ab1 and Cry35Ab1 proteins in soil were reported under Laboratory study ID 000365 (MRID Number 45242214).

The *cry34Ab1* and *cry35Ab1* genes code for the same Cry34Ab1 and Cry35Ab1 proteins as those characterized in Narva *et al.*, 2000 (MRID Number 45242201). Codon changes were made to lessen the likelihood of open reading frames (ORFs) in the gene inserts; however, the protein sequence and activity of the insecticidal crystal protein were not altered.

Because the proteins share identical amino acid sequences, the soil-degradation data contained in MRID Number 45242214 support this new EUP application. These data illustrate the degradation of Cry34Ab1 and Cry35Ab1 proteins in soil.

Study Title	MRID Number
Degradation of Microbial Binary PS149B1 Delta-Endotoxin in a Representative Soil from the Midwestern USA Maize-Growing Region	45242214

SECTION F. TOLERANCE PROPOSAL

Experimental Use Permit

***Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal protein as expressed in maize**

A temporary tolerance petition was previously submitted (March 2001) and is currently under review at EPA. All activities for this EUP will be conducted on a 'non-crop destruct' basis for food and feed use, but will maintain 'crop-destruct' for environmental containment.

SECTION G. PROPOSED EXPERIMENTAL PROGRAM

Experimental Use Permit

***Bacillus thuringiensis* Cry34/35Ab1 insecticidal crystal proteins as expressed in maize**

Data in support of this section is contained in Volume 2 of this application

VOLUME 2

PROPOSED EXPERIMENTAL PROGRAM

PHP17658

Section G: Proposed Experimental Program

Experimental Use Permit Request
For
***BACILLUS THURINGIENSIS* CRY34/35Ab1**
INSECTICIDAL CRYSTAL PROTEIN AS EXPRESSED IN
MAIZE -
CONSTRUCT PHP17658

October 17, 2002

Submitted By:

Pioneer Hi-Bred International, Inc.
7250 NW 62nd Avenue
Johnston, Iowa 50131

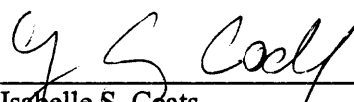
STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10(d) (1) (A), (B), or (C).

These data are the property of Pioneer Hi-Bred International, Inc. (Pioneer), and as such, are considered to be confidential for all purposes other than compliance with FIFRA §10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality that may exist under any other statute or in any other country.

Company: Pioneer Hi-Bred International, Inc.

Company Agent:


Isabelle S. Coats
Associate Registration Manager

Date: October 17, 2002

**BACILLUS THURINGIENSIS CRY34/35Ab1 INSECTICIDAL
CRYSTAL PROTEIN AS EXPRESSED IN MAIZE**

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SECTION G: PROPOSED EXPERIMENTAL PROGRAM

Section G: Proposed Experimental Program

1. Participants

The experimental use program will be under the overall management of the following scientists:

Isabelle S. Coats, Ph.D.
Associate Registration Manager
Pioneer Hi-Bred International, Inc.
7250 NW 62nd Avenue
Johnston, IA 50131

Paul Olson, Ph.D.
Research Manager-Disease Resistance
Pioneer Hi-Bred International, Inc.
7300 N. W. 62nd Avenue
Johnston, IA 50131

Laura Higgins, M.S.
Research Scientist - Insect
Control/Herbicide Resistance
Pioneer Hi-Bred International, Inc.
7300 N. W. 62nd Avenue
Johnston, IA 50131

2. Target Pest and Overview of Experimental Program

The target pests to be evaluated in the proposed experimental program are *Diabrotica virgifera virgifera*, Western corn rootworm (WCRW), and *Diabrotica berberis*, Northern corn rootworm (NCRW). Both insects are major pests of maize in North America. The development of transgenic maize expressing the binary ICP (insecticidal crystal protein) endotoxin will provide growers with a simple, highly effective, and environmentally benign means of controlling both rootworms. The transgenic maize tested under this EUP for plantings from March 2003 to March 2004 will be the first to use a CRY34/35Ab1 binary ICP derived from *Bacillus thuringiensis* strain PS149B1. Laboratory tests and small plot trials with transgenic CRY34/35Ab1 maize have shown that CRY34/35Ab1 has activity on corn rootworms (*Diabrotica* sp.). Further field testing across 19 states will continue to evaluate the efficacy of the CRY34/35Ab1 binary ICP.

Additional objectives under the EUP experimental program include, conversion to commercial varieties, observation of agronomic potential, studies in resistant management and research into other commercial determinants. The proposed field protocols for these objectives are listed below in summary format. A complete description of each field protocol can be found on pages 7 through 24.

EUP Protocols	Acres	Lbs. of Seed
B.t. Cry34/35Ab1 Insect Resistance Management Trial	0.150	2.501
B.t. Cry34/35Ab1 Maize Agronomic Observation Trial	160.607	2,680.653
B.t. Cry34/35Ab1 Maize Breeding and Observation Nursery Trial	348.200	5,804.494
B.t. Cry34/35Ab1 Maize Demonstration Trial	5.202	86.717
B.t. Cry34/35Ab1 Maize Efficacy Trial	6.750	112.523
B.t. Cry34/35Ab1 Maize Hybrid Production Plots Trial	39.500	658.465
B.t. Cry34/35Ab1 Maize Regulatory Field Studies Trial	31.492	524.972
B.t. Cry34/35Ab1 Non-Target Trial	2.576	42.942
Herbicide Tolerance Study	27.750	462.593
Total	622.427	10,375.858

3. States and Acreage

**PROPOSED EXPERIMENTAL USE PROGRAM
FOR PLANTINGS FROM MARCH 2003 THROUGH MARCH 2004**

States	Maximum Transgenic Acres	Locations	Maximum Transgenic Seed	Max. Cry34Ab1 Protein in Seed Planted (grams) (32.5 ug per g dry weight)	Max. Cry35Ab1 Protein in Seed Planted (grams) (16.9 ug per g dry weight)
CA	2.875	2	71,875	0.706 g	0.037 g
GA	1.700	2	42,500	0.418 g	0.022 g
HW	339.850	8	8,496,250	83.501 g	4.342 g
IA	60.106	10	1,502,650	14.768 g	0.768 g
IL	46.656	11	1,166,400	11.463 g	0.596 g
IN	19.840	5	496,000	4.875 g	0.253 g
KS	7.236	6	180,900	1.778 g	0.092 g
MI	6.388	3	159,700	1.57 g	0.082 g
MN	21.072	7	526,800	5.177 g	0.269 g
MO	7.066	3	176,650	1.736 g	0.09 g
ND	6.850	3	171,250	1.683 g	0.088 g
NE	24.600	5	615,000	6.044 g	0.314 g
OH	3.280	6	82,000	0.806 g	0.042 g
PA	4.052	3	101,300	0.996 g	0.052 g
PW	45.150	6	1,128,750	11.093 g	0.577 g
SD	1.450	3	36,250	0.356 g	0.019 g
TN	1.950	2	48,750	0.479 g	0.025 g
TX	2.730	5	68,250	0.671 g	0.035 g
WI	19.576	7	489,400	4.81 g	0.25 g
TOTALS	622.427	97	15,560,675	152.93 g	7.952 g

***B.t.* CRY34/35Ab1 Insect Resistance Management Trial**

Objective

These studies will provide information for the development of IRM strategies for genetically modified *B.t.* CRY34/35Ab1 maize lines expressing the binary ICP (insecticidal crystal protein). Specific experiments will focus on the determination of high dose against Western corn rootworm.

Description

Lines of each transformation event will be planted in up to four replications of a randomized design. Each line may be represented both by a segregate with the binary ICP and a segregate without the binary ICP. Experimental units will contain up to 3,000 plants. Plants will be artificially infested with Western corn rootworm or a natural infestation will be used. Data on the number of adults emerging from *B.t.* CRY34/35Ab1 plants versus non- *B.t.* CRY34/35Ab1 plants will be collected at various times during the growing season. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test materials will consist of dent corn of varying genetic constitution containing:

Vectors	Events
PHP17658	E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number of locations
IA	2

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 0.050 acres per planting, not including area required for isolation, if used.

Schedule

Maximum number of plantings per site: up to two plantings per site.

Planting Dates: 3/1/03 - 8/1/04

Harvest Dates: 6/1/03 – 11/30/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting. (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissue, whole plant samples, and/or insect samples may be taken up to ten times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Any remaining vegetative material will be tilled into the soil at the trial site. Unwanted seed maybe returned to the site prior to cultivation for soil composting. Seed and plant material produced in these trials may be used for analyses or saved for further research or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

***B.t.* CRY34/35Ab1 Maize Agronomic Observation Trial**

Objective

Assess agronomic and phenotypic effects of the binary ICP (insecticidal crystal protein) in genetically modified *B.t.* CRY34/35Ab1 maize lines.

Description

B.t. CRY34/35Ab1 maize lines will be observed for yield and other agronomic and phenotypic effects of insertion of the ICP. Plants may be treated with herbicide, and/or infested with Western corn rootworm or other corn insects, and/or sampled for various laboratory analyses to determine phenotype and segregation patterns. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test material will consist of dent corn of varying genetic constitution containing:

Vectors
PHP17658

Events
E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number of locations	State	Number of locations
CA	2	ND	3
GA	4	NE	5
HI	6	OH	2
IA	7	PA	2
IL	10	PR	6
IN	4	SD	2
KS	2	TN	2
MI	2	TX	2
MN	6	WI	6
MO	2		

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.00 acre per planting, not including area required for isolation, if used.

Schedule

Maximum number of plantings: Hawaii and Puerto Rico - up to 4 cycles with up to 5 plantings for a total of 20 plantings per year; all other states - up to 2 plantings per year.

Planting Dates: 3/1/03 - 3/1/04

Harvest Dates: 6/1/03 – 6/1/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting. (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissue and/or whole plant samples may be taken several times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Any remaining vegetative material will be tilled into the soil at the trial site. Unwanted seed may be returned to the site prior to cultivation for soil composting. Seed and plant material produced in these trials may be used for analyses or saved for further research or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

***B.t.* CRY34/35Ab1 Maize Breeding and Observation Nursery Trial**

Objective

Through backcrossing, selfing, and observation of phenotype, convert non-genetically modified or genetically modified inbred lines to genetically modified *B.t.* CRY34/35Ab1 maize lines expressing the binary ICP (insecticidal crystal protein) and maintain these lines all the way to seed production.

Description

Using various experimental plot designs, *B.t.* CRY34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed. Plants may be treated with herbicide, and/or infested with Western corn rootworm or other corn insects, and/or sampled for various laboratory analyses to determine phenotype and segregation patterns. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test materials will consist of dent corn of varying genetic constitution containing:

Vectors	Events
PHP17658	E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number of locations	State	Number of locations
HI	6	MN	3
IA	7	ND	2
IL	10	NE	2
IN	4	PR	6
KS	2		

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.00 acre per planting, not including area required for isolation, if used.

Schedule

Maximum number of plantings: Hawaii and Puerto Rico - up to 4 cycles with up to 5 plantings for a total of 20 plantings per year; all other states - up to 2 plantings per year.

Planting Dates: 3/1/03 - 3/1/04

Harvest Dates: 6/1/03 – 6/1/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting . (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissue and/or whole plant samples may be taken several times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Any remaining vegetative material will be tilled into the soil at the trial site. Unwanted seed may be returned to the site prior to cultivation for soil composting. Seed and plant material produced in these trials may be used for analyses or saved for further research or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

***B.t.* CRY34/35Ab1 Maize Demonstration Trial**

Objective

Demonstrate the efficacy of genetically modified *B.t.* CRY34/35Ab1 expressing the binary ICP (insecticidal crystal protein) in controlling Western corn rootworm and/or other Coleopteran insects.

Description

Lines of each transformation event of *B.t.* CRY34/35Ab1 maize lines will be planted in plots of up to 4 rows by 30 feet in length. Each line may be represented both by a segregate without the ICP and a segregate with the ICP. Experimental units (rows) will contain up to 100 plants. Plants will be infested with Western corn rootworm, and/or other corn insects, and/or rely on natural infestations. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Locations

State	Number of locations	State	Number of locations
IA	3	MN	2
IL	4	MO	2
IN	2	NE	2
KS	2	PA	2
MI	2	WI	2

Genotypes and Vectors

Test materials will consist of dent corn of varying genetic constitution containing:

Vectors
PHP17658

Events
E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.00 acre per planting, not including area required for isolation, if used.

Schedule

Maximum number of plantings per site: up to two plantings per site.
Planting Dates: 3/1/03 – 8/1/04
Harvest Dates: 6/1/03 – 11/30/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting. (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissue, whole plant samples, and/or insect samples may be taken up to ten times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Any remaining vegetative material will be tilled into the soil at the trial site. Unwanted seed may be returned to the site prior to cultivation for soil composting. Seed and plant material produced in these trials may be used for analyses or saved for further research or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

***B.t.* CRY34/35Ab1 Maize Efficacy Trial**

Objective

Assess the efficacy of genetically modified *B.t.* CRY34/35Ab1 maize lines expressing the binary ICP (insecticidal crystal protein) in controlling Western corn rootworm and/or other Coleopteran insects.

Description

B.t. CRY34/35Ab1 maize lines alone, or crossed with other genetically modified corn lines, will be planted in up to six replications of a randomized design. Each line may be represented both by a segregate without the ICP and a segregate with the ICP. Experimental units (rows) will contain up to 100 plants. Plants will be infested with Western corn rootworm and/or other Coleopteran insects, and/or rely on natural infestations. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test materials will consist of dent corn of varying genetic constitution containing:

Vectors
PHP17658

Events
E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number of locations	State	Number Of locations
HI	6	NE	2
IA	4	SD	3
IL	2	TN	2
IN	2	TX	2
KS	2	WI	2
MN	2		

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.0 acres per planting, not including area required for isolation, if used.

Schedule

Maximum number of plantings per site: Hawaii: up to 4 cycles with up to 5 plantings for a total of 20 plantings per year; all other states – up to 2 plantings per year.

Planting Dates: 3/1/03 - 3/1/04

Harvest Dates: 6/1/03 – 6/1/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting . (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissue, whole plant samples, and/or insect samples may be taken up to ten times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Any remaining vegetative material will be tilled into the soil at the trial site. Unwanted seed may be returned to the site prior to cultivation for soil composting. Seed and plant material produced in these trials may be used for analyses or saved for further research or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

***B.t.* CRY34/35Ab1 Maize Hybrid Production Plots Trial**

Objective

Production of hybrid seed for use in research strip trials and other forms of research testing.

Description

B.t. CRY34/35Ab1 maize lines expressing the binary ICP (insecticidal crystal protein) will be crossed with non-genetically modified or genetically modified lines to make hybrid seed for yield and agronomic testing. In addition, plants may be treated with herbicide, and/or infested with Western corn rootworm or other corn insects, and/or sampled for various laboratory analyses to determine phenotype. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test materials will consist of dent corn of varying genetic constitution containing:

Vectors	Events
PHP17658	E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number of Locations	State	Number of Locations
HI	6	KS	2
IA	6	MN	2
IL	7	NE	2
IN	3	PR	6

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.00 acres per planting.

Schedule

Maximum number of plantings per cycle: Hawaii and Puerto Rico: up to 4 cycles with up to 5 plantings for a total of 20 plantings per year; all other states – up to 2 plantings per year.

Planting Dates: 3/1/03 - 3/1/04

Harvest Dates: 6/1/03 – 6/1/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting . (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissue and/or whole plant samples may be taken several times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Plant material remaining after harvest may be may be returned to the plot for soil composting. Seed and plant material produced in these trials that is not saved for further research, analyses, or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

***B.t.* CRY34/35AB1 Maize Regulatory Field Studies Trial**

Objective

These studies will provide the test material (plant tissues) needed for regulatory studies with *B.t.* CRY34/35Ab1 maize lines expressing the binary ICP (insecticidal crystal protein).

Description

B.t. CRY34/35Ab1 maize lines will be planted at each location in up to seven replications of a randomized design. *B.t.* CRY34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed. Plants may be treated with herbicide and sampled for various laboratory analyses. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test materials will consist of dent corn of varying genetic constitution containing:

Vectors
PHP17658

Events
E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number Of Locations	State	Number Of Locations
IA	4	NE	4
IL	4	SD	2
IN	4	OH	4
KS	4	TX	4
MN	4	WI	4
MO	4		

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.25 acres per planting, not including area required for isolation, if needed.

Schedule

Maximum number of plantings per cycle: up to two plantings per site.

Planting dates: 3/1/03 - 8/1/04

Harvest dates: 6/1/03 – 11/30/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting. (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissue and/or whole plant samples may be taken several times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Plant material remaining after harvest may be returned to the plot for soil composting. Seed and plant material produced in these trials that is not saved for further research, analyses, or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

***B.t.* CRY34/35Ab1 Non-Target Trial**

Objective

These studies will provide information on the impact of corn rootworm control strategies on non-target arthropod populations commonly found in maize fields.

Description

B.t. CRY34/35Ab1 maize lines expressing the binary ICP (insecticidal crystal protein) will be planted in up to four replications of a randomized design. Experimental units will contain up to 3,000 plants. Populations of non-target arthropods will be monitored up to ten times during the growing season. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test materials will consist of dent corn of varying genetic constitution containing:

Vectors	Events
PHP17658	E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number of locations
IA	2
NE	3

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.25 acres per planting, not including area required for isolation, if used.

Schedule

Maximum number of plantings per site: up to two plantings per site.

Planting Dates: 3/1/03 - 8/1/04

Harvest Dates: 6/1/03 – 11/30/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting. (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of

transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4)
Detasseling of test plants prior to onset of anthesis.

Sampling

Sampling methods will include visual observations, sticky trap collections, pitfall traps, and soil samples to capture arthropods located above, on and below ground. All collected arthropods will be taken into a laboratory at Pioneer Hi-Bred for quantification and identification. Soil samples will also be taken into a laboratory at Pioneer Hi-Bred or other laboratory. A Berlese-Tullgren funnel system will be used to extract all arthropods from the sample. Soil will then be returned to the test site.

Plant tissue, and/or whole plant samples, may be taken up to ten times during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Any remaining vegetative material will be tilled into the soil at the trial site. Unwanted seed may be returned to the site prior to cultivation for soil composting. Seed and plant material produced in these trials may be used for analyses or saved for further research or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.

Herbicide Tolerance Study

Objective

Evaluate the effect of herbicide application on *B.t.* CRY34/35Ab1 genetically modified lines expressing the binary ICP (insecticidal crystal protein).

Description

B.t. CRY34/35Ab1 maize lines will be evaluated for resistance to applications of herbicide. Plants may be evaluated for yield, and for effects of herbicide on plant development and agronomic traits. *B.t.* Cry34/35Ab1 maize lines may be crossed with non-genetically modified or genetically modified corn lines or selfed.

Genotypes and Vectors

Test material will consist of dent corn of varying genetic constitution containing:

Vectors	Events
PHP17658	E4497.66.1.27, E4497.71.1.29, E4497.71.1.33

Additional genetically modified and non-genetically modified lines may be included in the total plot acreage.

Locations

State	Number of locations	State	Number of locations
HI	6	MO	2
IA	5	NE	3
IL	7	OH	2
IN	3	PA	2
KS	2	PR	6
MN	4	WI	4

Acreage per Site

Acres of genetically modified lines expressing the binary ICP: up to 1.50 acres per planting, not including area required for isolation, if used.

Schedule

Maximum number of plantings: Hawaii and Puerto Rico - up to 4 cycles with up to 5 plantings for a total of 20 plantings per year; all other states - up to 2 plantings per year.

Planting Dates: 3/1/03 - 3/1/04

Harvest Dates: 6/1/03 – 6/1/04

Border rows

The entire trial site will be surrounded by at least ten rows of an appropriate corn line.

Isolation

One or more of the following methods may be used: (1) Transgenic plants will be located at least 660 feet from receptive silks on corn intended for commercial sale or replanting . (2) Tassels will be kept bagged from prior to anthesis until pollen shed is complete or until tassel is removed from the plant. (3) Temporal shift with monitoring, where the flowering period of transgenic plants will not coincide with presence of receptive silks on plants within 660 feet. (4) Detasseling of test plants prior to onset of anthesis.

Sampling

Plant tissues (e.g., whole plants and grain) will be collected up to two times at each location during the growing season and returned to Pioneer Hi-Bred, Dow AgroSciences, or other laboratories for analyses.

Harvest Procedures

Plots will be harvested by hand or mechanically. If by hand, ears will be placed in cloth or mesh bags of such construction to avoid loss of seed outside of the bags. If machine harvested, seed will be shelled as part of the process. The harvest machine will be thoroughly cleaned prior to exiting from the plot area.

Final Disposition

Any remaining vegetative material will be tilled into the soil at the trial site. Unwanted seed may be returned to the site prior to cultivation for soil composting. Seed and plant material produced in these trials may be used for analyses or saved for further research or future plantings. Unwanted experimental seed will be destroyed.

Volunteer Plants

Volunteer plants will be minimized by growing transgenic material in defined areas in the field and by performing termination procedures outlined above. The use of stakes, other physical markers, or global positioning systems to define the area where the transgenic plants are grown will be used to identify volunteers for later elimination.